UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,059	12/10/2003	Michael A. Centanni	ST8613US	8624

22203 7590 09/18/2008

KUSNER & JAFFE
HIGHLAND PLACE SUITE 310
6151 WILSON MILLS ROAD
HIGHLAND HEIGHTS, OH 44143

EXAMINER
CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,059	CENTANNI, MICHAEL A.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This non-final is in response to the RCE/Amendment received on 8/11/08

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 17, 20, 22, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331) and Kazi et al (U.S.P.N. 5,578,280).

Regarding claim 17, Pai teaches a method for deactivation using a combination of vaporous or gaseous chemicals (col.6, lines 5-12 and col.8, lines 1-3) where conventional sterilants (col.4, lines 50-54) such as vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) are combined. One of ordinary skill in the art upon reading Pai would recognize that sources for generating vaporized hydrogen peroxide and ozone are parts of the teachings of this reference. As to the added

limitation of inactivating biocontamination, Pai teaches reducing or eliminating microorganisms or their ability to reproduce (col.5, lines 37-40) where one of ordinary skill in the art would realize that items contaminated with microorganisms (considered as biocontaminants) are inactivated. As to the limitation of simultaneously introducing the vaporized hydrogen peroxide and the ozone gas into the region, Pai teaches combining vaporized hydrogen peroxide and ozone without teaching the simultaneous introduction of both sterilants. However, one of ordinary skill in the art would recognize that only three ways of introducing the sterilants are possible, where either one sterilant is introduced first before the other sterilant, or one sterilant is introduced after the other sterilant has already been introduced, or the simultaneous introduction of both sterilants. In addition, like the Pai reference, Applicant teaches combining ozone and vaporized hydrogen peroxide (page 3, paragraphs 0013, 0015, and 0021), or the simultaneous introduction of both sterilants (paragraph 0001), or decontaminating with ozone alone (paragraph 0048), or decontaminating with vaporous hydrogen peroxide alone (paragraph 0047). The specification does not teach advantages or unexpected results for the simultaneous introduction of both sterilants. As such one of ordinary skill in the art would realize upon reading the Pai reference and the specification that the order of introducing the sterilants is an obvious matter that is well within the purview of the artisan as evidenced by the Pai reference and Applicant's disclosure. Only the predicted results are attained.

Pai fails to teach the following: circulating a carrier gas; generating vaporized hydrogen peroxide using a vaporizer disposed in the conduit downstream of the ozone

generator; a removing moisture step by using a dryer; removing moisture from all of the carrier gas; generating ozone gas using oxygen molecules of the carrier gas; and a vapor hydrogen peroxide destroying step.

Childers discloses a method for vapor hydrogen peroxide decontamination of medical items in a sealable chamber (figure 7:10) that includes the following: circulating a carrier gas (page 7, lines 23-26) through a closed loop system (see the directional arrows in figure 6) so that superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters (page 5, lines 25-37); the closed loop system is comprised of a conduit (figure 7:16) and a region (figure 7:10) where the conduit (16) is fluidly connected with the region at an inlet and an outlet of the region (figure 7:14, 16, and 12) and wherein the carrier gas is circulated by a blower (figure 7:22a, 22b) disposed within the conduit (figure 7:16); removing moisture from the carrier gas using a drying means (figure 7:28 and page 5, lines 27-30) disposed in the conduit (the conduit is considered made up of parts16, 34, and 36 as shown in figure 7) in order to maintain a preselected percent saturation of the decontaminant vapor in the chamber (page 3, lines 33-34); introducing vaporized hydrogen peroxide into the conduit (figure 7:18, 16, 34, and 36), where the vaporized hydrogen peroxide is produced by a vaporizer (figure 7:18) disposed within the conduit (figure 7:18, 16, 34, and 36); and destroying vaporized hydrogen peroxide removed from the region through the outlet (figure 7:12, 10, 14, and 20), wherein the vaporized hydrogen peroxide is destroyed by a destroyer disposed in the conduit (page 8, lines 13-19) in order to make the vaporized hydrogen peroxide suitable for disposal

(page 8, lines 14-19) as water and oxygen. Childers places the vaporizer (figure 7:18) just before the inlet port into the region such that one of ordinary skill in the art would recognize that Childers intent is to introduce vapor hydrogen peroxide as the last input into the circulating gas entering the region (figure 7:18, 12, and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method in Pai with the sterilant/carrier gas recirculating closed loop system of Childers, because superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters as explained by Childers (page 5, lines 25-37). As to the limitation of introducing vaporized hydrogen peroxide downstream of the ozone generator, Childers already teaches introduction of hydrogen peroxide closest to the sterilizer. It would have been obvious to introduce ozone upstream of the hydrogen peroxide in order to incorporate ozone into the carrier gas, and adjust the temperature of such, prior to introduction of the hydrogen peroxide in order to limit adverse effects of the ozone on the temperature and pressure of the hydrogen peroxide vapor.

Pai and Childers fail to teach removing moisture from all of the carrier gas to be received by the ozone generator and generating ozone gas using oxygen molecules of the carrier gas. Kazi produces ozone (figure 7:63, 84, and 66) in a circulating air loop system (figure 7:80, 60 and col.17, lines 30-34) using the molecules of the circulating gas to generate ozone gas (col.17, lines 31-34). This results in producing ozone with high concentration over a shorter period of time when compared to other ozone generators (col.17, lines 35-42). Kazi further teaches that the air entering the ozone

generator must be first filtered and dried (col.14, lines 49-50 and 46-47. This is considered as removing moisture from all of the carrier gas) in order to prevent reducing the efficiency of the ozone generator (col.14, lines 55-56). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers with the air mixture circulating ozone generator, because such a generator results in the efficient production of ozone with high concentration over a shorter period of time in comparison to other ozone generators as explained b y Kazi (col.17, lines 35-42 and col.14, lines 55-56) and to further provide the modified method in Pai/Childers with drying all of the circulating gas prior to entering the ozone generator in order to prevent reducing the efficiency of the ozone generator as taught by Kazi (col.14, lines 55-56).

Regarding claim 20, Pai and Childers fail to teach producing ozone gas from the circulating carrier gas using an electrical discharge. Kazi produces ozone (figure 7:63, 84, and 66) using a corona discharge apparatus (figure 1:1) in a circulating air loop system (figure 7:80, 60, 63, 84, 66, and col.17, lines 30-34) using the circulating gas (col.17, lines 31-34), because it results in producing ozone with high concentration over a shorter period of time when compared to other ozone generators (col.17, lines 35-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers with the air mixture circulating ozone generator, because such a generator results in the efficient production of ozone with high concentration over a shorter period of time in comparison to other ozone generators as explained by Kazi (col.17, lines 35-42 and col.14, lines 55-56).

Regarding claim 22, Pai teaches combining conventional sterilants (col.4, lines 50-54) such as vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) where on of ordinary skill in the art upon reading Pai would recognize that the presence of an ozone generator is a part of the teachings of this reference. However, Pai and Childers fail to teach monitoring the concentration of ozone gas. Kazi produces ozone (figure 7:63, 84, and 66) in a circulating air loop system (figure 7:80, 60, 63, 84, 66, and col.17, lines 30-34) where the concentration of ozone in the final produced mixture is increased (col.16, lines 26-29) .One of ordinary skill in the art would, upon reading the Kazi reference, recognizes that Kazi monitors the concentration of the generated ozone in order to ascertain the amount of ozone increase in the produced gaseous sterilant. It would have been obvious to one of ordinary skill in the art at the time of the invention to monitor the concentration of ozone in the modified method in Pai/Childers/Kazi in order to determine when the concentration of ozone was sufficient to sterilize.

Regarding claims 25-26 and 28, Pai fails to teach that the sterilization system includes heating the recirculating carrier gas that includes air and destroying vapor hydrogen peroxide. Childers heats the recirculating carrier gas that includes air (figure 7:58a, 58b, 18, and page 5, lines 10-11) in order to control the temperature of the carrier gas entering the vaporizer (page 8, lines 34-37). Childers also destroys vapor hydrogen peroxide (figure 7:20 and page 8, lines 15-19) so that vapor hydrogen peroxide is decomposed to water and oxygen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method

in Pai by heating the recirculating gas that includes air and destroying vapor hydrogen peroxide in order to control the temperature of the carrier gas entering the vaporizer and provide water and oxygen as products for disposal.

Regarding claim 27, both Pai and Childers fail to teach using a desiccant to remove moisture from the carrier gas. Kazi teaches that the air entering the ozone generator must be first filtered and dried (col.14, lines 49-50. This is considered removing moisture from the carrier gas) using a desiccating liquid (col.16, line 49) in order to prevent reducing the efficiency of the ozone generator (col.14, lines 55-56). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method in Pai/Childers by using a desiccant to remove moisture in order to prevent reducing the efficiency of the ozone generator.

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331) and further in view of Kazi et al (U.S.P.N. 5,578,280) and Centanni et al (U.S.P.N. 7,087,805).

Pai teaches a method for deactivation using a combination of vaporous or gaseous chemical (col.6, lines 5-12 and col.8, lines 1-3) where conventional sterilants (col.4, lines 50-54) such as vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) are combined. One of ordinary skill in the art upon reading Pai would recognize that sources for generating vaporized hydrogen peroxide and ozone are parts of the teachings of this reference. As to the added limitation of inactivating biocontamination, Pai teaches reducing or eliminating microorganisms or their ability to reproduce (col.5, lines 37-40) where one of ordinary skill in the art would realize that

items contaminated with microorganisms (considered as biocontaminants) are inactivated. Pai fails to teach the following: circulating a carrier gas; generating vaporized hydrogen peroxide using a vaporizer disposed in the conduit downstream of the ozone generator; a removing moisture step by using a dryer; removing moisture from all of the carrier gas; generating ozone gas using oxygen molecules of the carrier gas; a vapor hydrogen peroxide destroying step; and simultaneously introducing vaporized hydrogen peroxide and ozone gas into the region.

Childers discloses a method for vapor hydrogen peroxide decontamination of medical items in a sealable chamber (figure 7:10) that includes the following: circulating a carrier gas (page 7, lines 23-26) through a closed loop system (see the directional arrows in figure 6) so that superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters (page 5, lines 25-37); the closed loop system is comprised of a conduit (figure 7:16) and a region (figure 7:10) where the conduit (16) fluidly connected with the region at an inlet and an outlet of the region (figure 7:14, 16, and 12) and wherein the carrier gas is circulated by a blower (figure 7:22a, 22b) disposed within the conduit (figure 7:16); removing moisture from the carrier gas using a drying means (figure 7:28 and page 5, lines 27-30) disposed in the conduit (the conduit is considered made up of parts16, 34, and 36 as shown in figure 7) in order to maintain a preselected percent saturation of the decontaminant vapor in the chamber (page 3, lines 33-34); introducing vaporized hydrogen peroxide into the conduit (figure 7:18, 16, 34, and 36), where the vaporized hydrogen peroxide is produced by a vaporizer (figure 7:18) disposed within

the conduit (figure 7:18, 16, 34, and 36); and destroying vaporized hydrogen peroxide removed from the region through the outlet (figure 7:12, 10, 14, and 20), wherein the vaporized hydrogen peroxide is destroyed by a destroyer disposed in the conduit (page 8, lines 13-19) in order to make the vaporized hydrogen peroxide suitable for disposal (page 8, lines 14-19) as water and oxygen. Childers places the vaporizer (figure 7:18) just before the inlet port into the region such that one of ordinary skill in the art would recognize that Childers intent is to introduce vapor hydrogen peroxide as the last input into the circulating gas entering the region (figure 7:18, 12, and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method in Pai with the sterilant/carrier gas recirculating closed loop system, because superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters as explained by Childers (page 5, lines 25-37). As to the limitation of introducing vaporized hydrogen peroxide downstream of the ozone generator, it would have been obvious to one of ordinary skill in the art to add the ozone upstream of the hydrogen peroxide in order to adjust temperature and pressure of the steam with ozone prior to introduction of hydrogen peroxide in order to minimize ill effects of combining streams on the hydrogen peroxide vapor, which is sensitive to temperature and pressure.

Pai and Childers fail to teach removing moisture from all of the carrier gas to be received by the ozone generator; generating ozone gas using oxygen molecules of the carrier gas; and simultaneously introducing vaporized hydrogen peroxide and ozone

gas into the region. Kazi produces ozone (figure 7:63, 84, and 66) in a circulating air loop system (figure 7:80, 60 and col.17, lines 30-34) using the molecules of the circulating gas to generate ozone gas (col.17, lines 31-34), because it results in producing ozone with high concentration over a shorter period of time when compared to other ozone generators (col.17, lines 35-42). Kazi further teaches that the air entering the ozone generator must be first filtered and dried (col.14, lines 49-50 and 46-47. This is considered as removing moisture from all of the carrier gas) in order to prevent reducing the efficiency of the ozone generator (col.14, lines 55-56). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers with the air mixture circulating ozone generator, because such a generator results in the efficient production of ozone with high concentration over a shorter period of time in comparison to other ozone generators as explained b y Kazi (col.17, lines 35-42 and col.14, lines 55-56) and to further provide the modified method in Pai/Childers with drying all of the circulating gas prior to entering the ozone generator in order to prevent reducing the efficiency of the ozone generator as taught by Kazi (col.14, lines 55-56).

Kazi fails to teach simultaneously introducing vaporized hydrogen peroxide and ozone gas into the region. Centanni discloses a method of neutralizing chemical and biological warfare agents (col.1, lines 7-10) by using ozone combined with a fluid medium (ozone vehicle) that includes hydrogen peroxide (col.3, lines 50-53), because it enhances the beneficial properties of ozone. Centanni further teaches that in one embodiment, ozone gas is simultaneously introduced with the introduction and agitation

of the organic solution (col.4, lines 17-19) where one of ordinary skill in the art would recognize that hydrogen peroxide is considered as a component of this solution, because of its ozone-enhancing properties. Moreover, Centanni applies ozone gas mixture to contaminated environment, for contact with airborne contaminants (col.8, lines 48-50) where hydrogen peroxide is combined with the ozone gas in order to form activated species (col.8, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers/Kazi with the simultaneous introduction of hydrogen peroxide and ozone, because hydrogen peroxide enhances the beneficial properties of ozone as taught by Centanni (col.3, lines 50-53).

5. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331) and Kazi et al (U.S.P.N. 5,578,280) as applied to claim 17 and further in view of Bell et al (U.S.P.N. 5,516,493).

Regarding claim 21, Pai, Childers, and Kazi fail to teach that using ultraviolet light leads to producing ozone. Bell generates ozone and further teaches that ultraviolet light contribute to ozone formation (col.7, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers/Kazi with the ultraviolet source since ultraviolet light enhances the production of ozone as explained by Bell (col.7, lines 5-7).

Regarding claim 23, Pai combines vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) where multiple sensors are used to insure that the

concentration of each sterilant is maintained within certain sterilization ranges. One of ordinary skill in the art would recognize that as the concentrations of hydrogen peroxide and ozone deviate from their target values during sterilization cycles, additions (modification) of the generated sterilants are required to maintain the concentrations of the sterilants within the target ranges.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331), Kazi et al (U.S.P.N. 5,578,280) as applied to claim 17 and further in view of Karlson (U.S.P.N. 5,069,880).

Pai, Childers, and Kazi fail to teach disposing an ozone destroyer in a supplemental conduit fluidly connected with the conduit downstream of the region. Karlson places an ozone destroyer (figure 8:W) in a supplemental conduit (unlabeled line connecting the top of tank B with destroyer W through valve L in figure 8) since with such a system the destroyer controls the generation of ozone by monitoring its temperature (col.7, lines 63-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers/Kazi with the ozone destroyer placed in a supplemental conduit, since with such a system the destroyer controls the generation of ozone by monitoring its temperature as explained by Karlson (col.7, lines 63-66).

Response to Arguments

7. Applicant's arguments with respect to claims 17 and 20-28 have been considered but are moot in view of the new ground(s) of rejection.

On pages 6 and 9 of the Remarks/Arguments section, Applicant argues with regard to the synergistic benefit of generating hydroxyl radicals as a result of the simultaneous introduction of both the vaporized hydrogen peroxide and ozone gas. However, the specification does not teach this recognition of synergistic effect due to simultaneous introduction of both sterilants.

On page 8 of the Remarks/Arguments section, Applicant argues that Childers only teaches the partial and selective removal of moisture of the carrier gas. Instant claim 17 does not require the complete removal of all moisture from the recirculating carrier gas. It requires removing moisture from all of the carrier gas without leaving any part of the carrier gas not having removed moisture from it.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797